# Implementation Research: Case studies

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Policy Forum

# Defining Research to Improve Health Systems

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## Summary Points

- Research has an important role to play in strengthening health systems to improve system performance and public health impact.
- The multiple definitions of operational research, implementation research, and health systems research creates confusion and negatively affects the credibility and progress of the research.
- The aim of this paper is to present working definitions of operational research, implementation research, and health systems research to provide greater clarity for non-specialists, scientists, policymakers, and donors working to strengthen health systems.

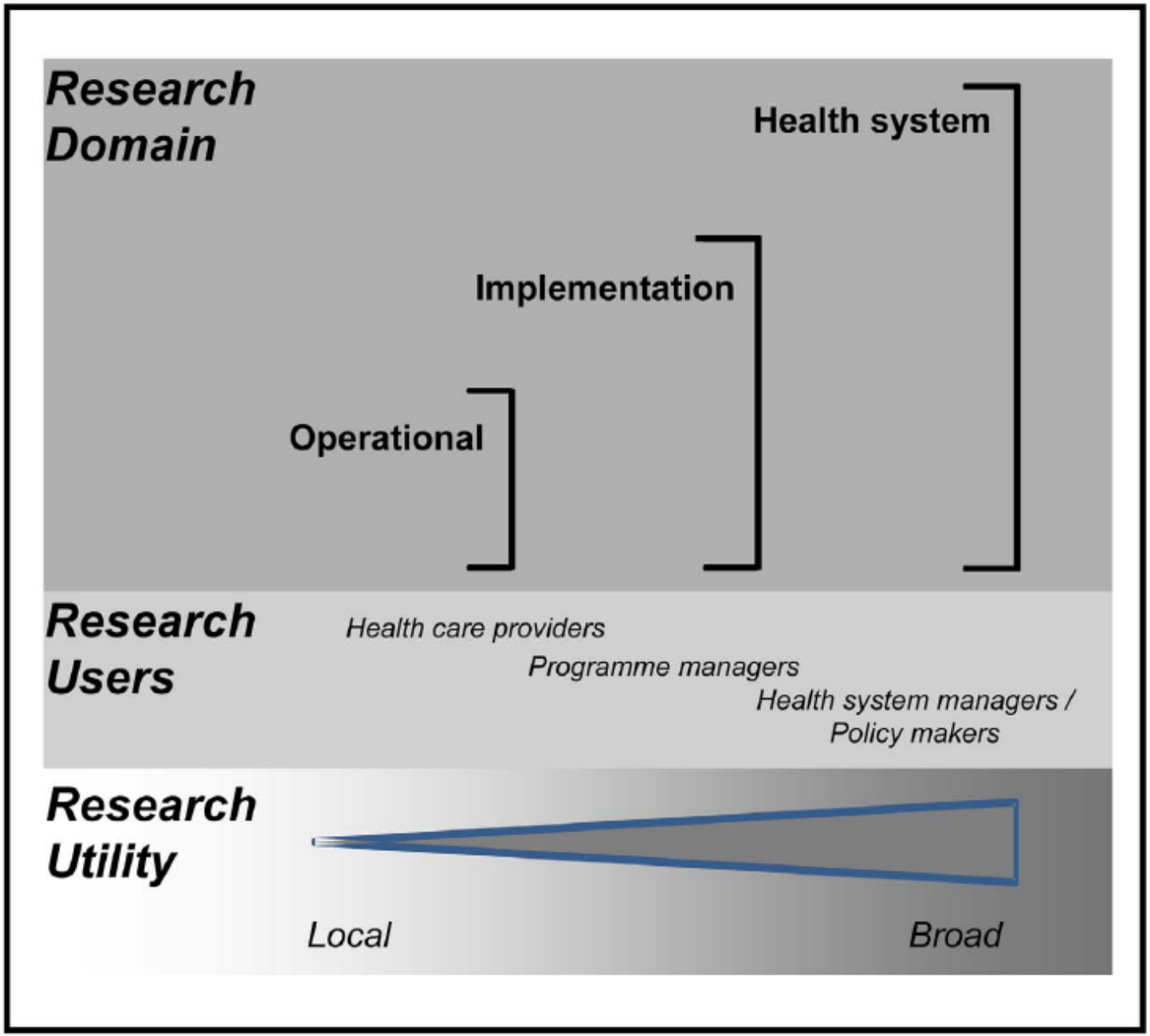


**Figure 1. Research to improve health systems.**
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**Table 1.** Defining research to improve health systems.

| Research Domain | Primary Characteristic | | |
|---|---|---|---|
| | **Focus of the Research** | **Users of the Research Outputs** | **Utility of the Research Outputs*** |
| **Operational** | Operational issues of specific health programmes | Health care providers programme managers | Local |
| **Implementation** | Implementation strategies for specific products or services | Programme managers, R&D managers | Local/broad |
| **Health System** | Issues affecting some or all of the building blocks of a health system | Health system managers, policy makers | Broad |

*How amenable the research outputs are to adaptation, scaling up or use or in other contexts or locations.

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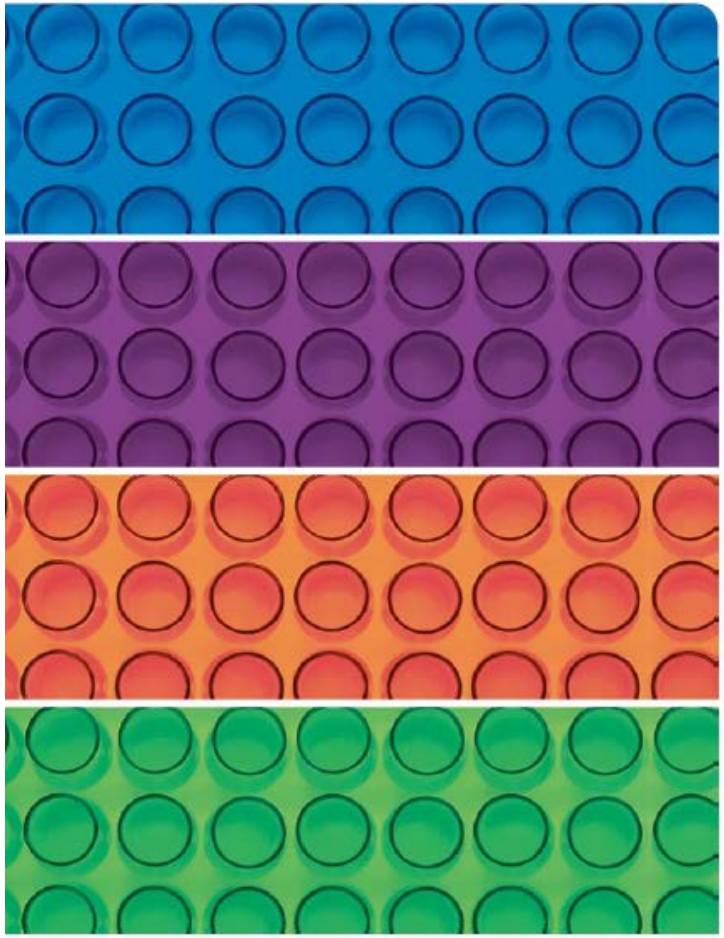

# Framework for Operations and Implementation Research in Health and Disease Control Programs

Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

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FROM THE AMERICAN PEOPLE

World Health Organization

TDR

UNAIDS

The World Bank
Global HIV/AIDS
Program

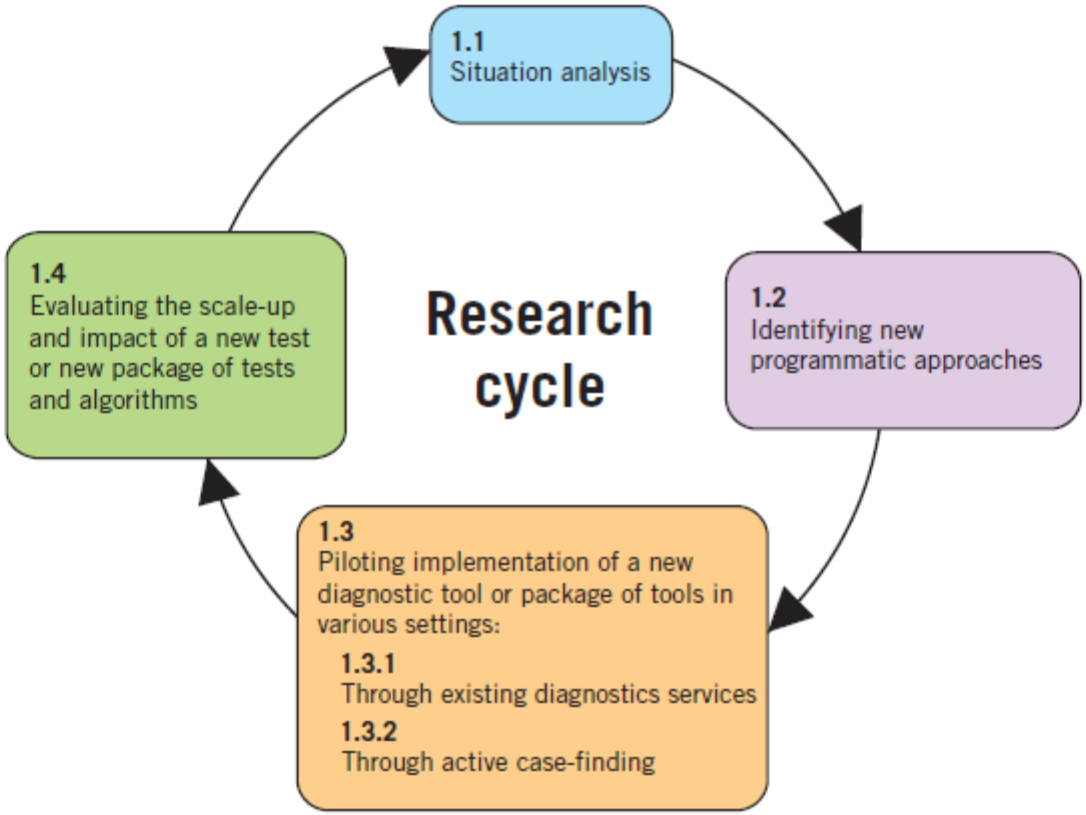
# Priorities in Operational Research to Improve Tuberculosis Care and Control

Stop TB Partnership

The Global Fund

World Health Organization

**FIGURE 2.** CYCLE OF RESEARCH ACTIVITIES FOR IMPROVED ACCESS, SCREENING AND DIAGNOSIS OF TB



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# Using a bus service for transporting sputum specimens to the Central Reference Laboratory: effect on the routine TB culture service in Malawi

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# Background

- Malawi Central Reference Laboratory (CRL) set up in Lilongwe in 1988 to provide national TB culture and drug susceptibility testing service (CDST).
- Malawi NTP aims to follow WHO guidelines
- Patients registered as having previous TB asked to submit two further sputum specimens for CDST before starting recommended re-treatment regimen.
- Specimens sent to CRL, reports returned to peripheral unit
- Until 1999, peripheral units made their own arrangements for sending sputum specimens to CRL

# Situational analysis/identifying implementation problems and their main determinants

**Table 1** Efficiency of the sputum culture and drug sensitivity testing service from peripheral units to the CRL, 1992–1998

| Year | Patients registered with smear-positive PTB who had been previously treated *n* | Patients whose sputum specimens reached the CRL *n* (%) | Patients whose specimens were culture-positive for DST *n* (%) | Patients whose isolates were sensitive to TB drugs (S,H,R) *n* (%) |
|---|---|---|---|---|
| 1992 | 462 | 123 (27) | 54 (44) | 40 (74) |
| 1993 | 534 | 127 (24) | 54 (43) | 31 (57) |
| 1994 | 504 | 282 (56) | 75 (27) | 55 (73) |
| 1995 | 551 | 245 (44) | 105 (43) | 79 (75) |
| 1996 | 529 | 297 (56) | 144 (48) | 113 (78) |
| 1997 | 507 | 293 (58) | 143 (49) | 106 (74) |
| 1998 | 605 | 351 (58) | 173 (49) | 132 (76) |
| Total, 1992–1998 | 3692 | 1718 (47) | 748 (44) | 556 (74) |

CRL = Central Reference Laboratory, Lilongwe; PTB = pulmonary tuberculosis; DST = drug sensitivity testing; S = streptomycin; H = isoniazid; R = rifampicin.

# Develop practical solutions to the problems

In 1999, Malawi NTP approaches a bus company that served all districts in Malawi.

- Sputum specimens transported by bus from districts to Lilongwe bus terminus for collection by CRL staff

# Test whether new implementation strategies based on these solutions can significantly improve access under conditions of routine disease control

- How well is CDST service performing with new transport system?
- Carried out country-wide survey to assess the various stages in the process from registration of patients through to receipt of specimens by CRL to mycobacterial CDST

# Methods

- In 2001, 44 public, or private not-for-profit, hospitals registered and treated patients for TB (4 Central, 22 district and 18 Mission hospitals)
- All visited between April and June 2002.
- TB Officer interviewed using pro-forma questionnaire.
- Details obtained about sputum collection, transport arrangement and method of storage prior to transport.

- Data collected retrospectively from TB patient register in each hospital
- Patients with smear positive TB who were categorized as relapses, failures or treatment after default were identified
- Name, TB registration number, age, sex, date of registration and date of starting treatment were recorded. Sputum collection date and date that the sputum was sent to CRL if available
- Search made in TB office for returned CDST reports and these were counted if found.
- Details of previously-treated patients brought to CRL.

CDST registers in CRL were inspected:

- Arrived in CRL?
- Date of sputum collection in periphery (written on request form and transferred to CRL register)?
- Concentrated smear status of specimens processed at CRL including highest AFB smear grade of two specimens?
- Date that specimens were inoculated at the CRL for mycobacterial culture?
- Whether cultures were positive for Mtb with sufficient colonies  for DST

*Data analysis*

Data were entered using Epi Info software (Epi Info version 6.4, Centers for Disease Control and Prevention, Atlanta, GA) and cleaned twice by different individuals. Differences between groups were compared using $\chi^2$ test for categorical variables and $\chi^2$ test for trend, with differences at the 5% level being regarded as significant.

# Results

*Patient population*

In 2001, a total of 964 sputum smear-positive retreatment cases were registered in Malawi (excluding Karonga), 535 males and 429 females, with a mean age (standard deviation) of 36 (11) years. They included 860 relapse cases, 75 patients who had failed treatment and 29 who had returned to treatment after default.

**Table 3** Collection and transport of sputum specimens to the CRL: results of interviews with TB Officers

| | *n* (%) |
|---|---|
| Officer responsible for supervising the collection and transport of sputum to CRL | |
| TB Officer | 41 (100) |
| Site of sputum collection | |
| TB ward | 40 (98) |
| TB office | 1 (2) |
| Time of sputum collection | |
| Before start of treatment | 26 (63) |
| After start of treatment | 15 (37) |
| Storage of sputum prior to transport | |
| Refrigerator | 19 (46) |
| Room temperature | 22 (54) |
| Sputum transport boxes for buses | |
| In stock | 38 (93) |
| Sputum sent by bus to CRL | 30 (73) |
| Sputum sent by other transport to CRL | 11 (27) |
| Motor-cycle | 4 |
| Ambulance | 6 |
| Zonal (regional) TB Officer | 1 |
| Reasons for not using bus service | |
| No bus service in the district | 4 |
| Bus service refused to handle sputum | 3 |
| Hospital close to CRL | 2 |
| TB Officer not informed of bus service | 1 |
| None | 1 |
| CRL informed that sputum had been dispatched | 3 (7) |

CRL = Central Reference Laboratory, Lilongwe; TB = tuberculosis.

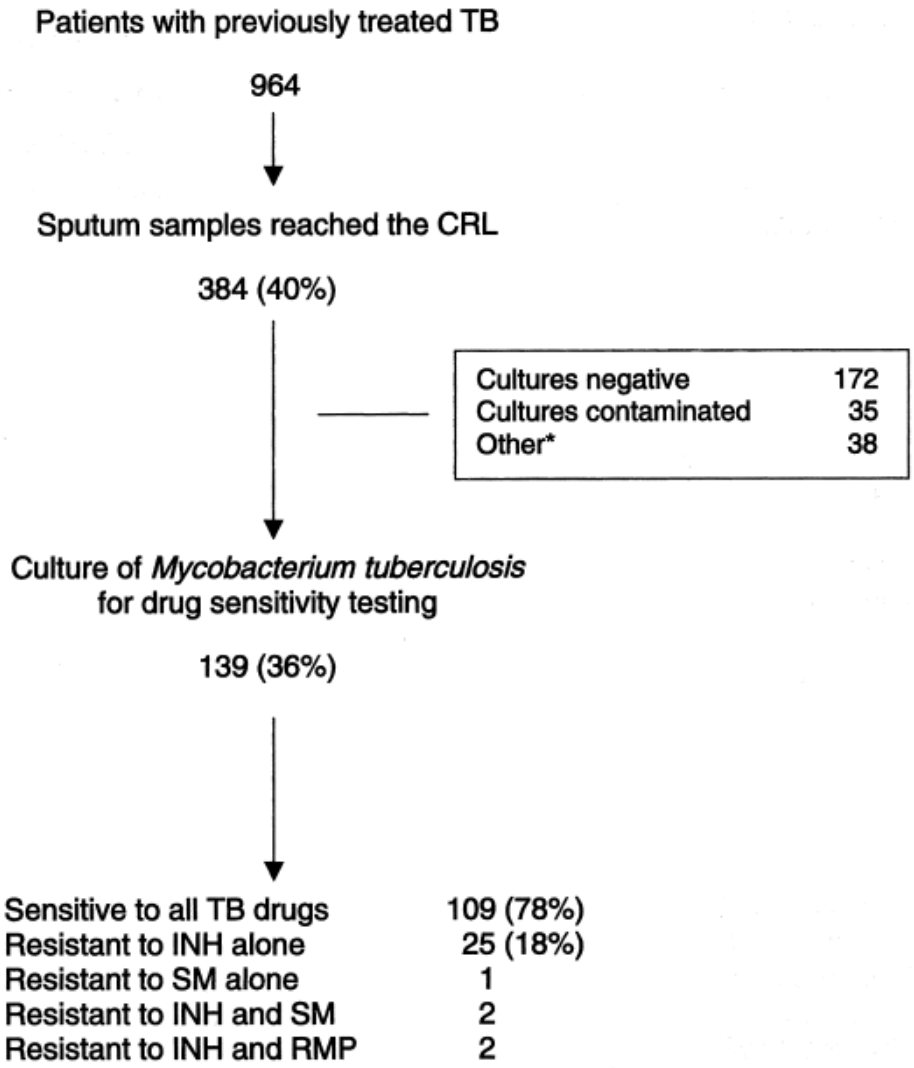


**Figure** Performance of the process from registration of patients to culture and DST at the Central Reference Laboratory, Lilongwe (CRL). * Other = cultures growing mycobacteria other than *M. tuberculosis* or insufficient colonies for DST. TB = tuberculosis; INH = isoniazid; SM = streptomycin; RMP = rifampicin; DST = drug sensitivity testing.

**Table 4** Factors associated with successful growth of *M. tuberculosis* for DST in specimens reaching the CRL

| Factor | Number of patients | Successful growth of *M. tuberculosis* for DST *n* (%) | $\chi^2$ test for trend (*P* value) |
|---|---|---|---|
| Time of sputum collection ($n = 370$) | | | |
| Before or on day of treatment | 87 | 37 (43) | $\chi^2 = 6.80$ |
| 1–3 days after treatment | 160 | 65 (41) | ($P < 0.01$) |
| 4 or more days after treatment | 123 | 32 (26) | |
| Days from sputum collection to inoculating specimens for culture at the CRL ($n = 384$) | | | |
| 1–10 | 77 | 27 (35) | $\chi^2 = 1.68$ |
| 11–20 | 88 | 36 (41) | ($P = 0.19$) |
| 21–30 | 84 | 36 (43) | |
| 31–40 | 64 | 20 (31) | |
| 41 or above | 71 | 20 (28) | |
| Smear examination of specimens that reached the CRL ($n = 384$) | | | |
| No AFB seen | 152 | 10 (7) | $\chi^2 = 102$ |
| AFB scanty | 12 | 3 (25) | ($P < 0.001$) |
| AFB 1+ | 16 | 5 (31) | |
| AFB 2+ | 37 | 23 (62) | |
| AFB 3+ | 167 | 98 (59) | |

DST = drug sensitivity testing; CRL = Central Reference Laboratory, Lilongwe; AFB = acid-fast bacilli.

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